Inspection Checklist for ABSL-4 Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; BMBL 5th Edition)

Inspection Date:

Entity Name:

Responsible Official:

SAP Inspector(s):

Principal Investigator (P.I.):

Laboratory Location - Street Address:

Building:

Room number(s):

Agent(s)/Toxin(s):

When Information is entered in this form, the form is to be considered "Sensitive Select Agent Information."

Reference	Statement	Response			Comments
		Yes	No	N/A	
CFR: Section 12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use.				
CFR: Section 12(a)	The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.				
CFR: Section 12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).				
CFR: Section 12 (c)(1)	In developing a biosafety plan, an individual or entity should consider: The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories, including all appendices. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, Pennsylvania, 75250-7954 or from the CDC website at http://www.cdc.gov/. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia.				
CFR: Section 12(d)	The plan must be reviewed annually and revised as necessary.				
CFR: Section 12(d)	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.				
CFR: Section 12(d)	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				
A					
BMBL: A1	The animal facility directors must establish and enforce policies, procedures, and protocols for biosafety, biosecurity and emergency situations within the ABSL-4 laboratory. The animal facility director and/or designated institutional officials are responsible for enforcing the policies that control access to the ABSL-4 facility.				
BMBL: A1	Laboratory personnel and support staff must be provided appropriate occupational medical service including medical surveillance and available immunizations for agents handled or potentially present in the laboratory.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: A1	A system must be established for reporting and documenting laboratory accidents, exposures, employee absenteeism and for the medical surveillance of potential laboratory associated illnesses. An essential adjunct to such an occupational medical services system is the availability of a facility for the isolation and medical care of personnel with potential or known laboratory acquired infections.				
BMBL: A1	Facility supervisors should ensure that medical staffs are informed of potential occupational hazards within the animal facility including those associated with research, animal husbandry duties, animal care and manipulations.				
BMBL: A1	An ABSL-4 laboratory specific, biosafety manual must be prepared in consultation with the animal facility director, the laboratory supervisor, and the biosafety advisor.				
BMBL: A1	The biosafety manual must be available and accessible.				
BMBL: A1	Personnel are advised of special hazards, and are required to read and follow instructions on practices and procedures.				
BMBL: A1	Prior to beginning a study, appropriate policies and procedures for animal welfare during the conduct of research, must be developed and approved by the IACUC. The biosafety official, the IBC and/or other applicable committees, are responsible for review of protocols and polices to prevent hazardous exposures to personnel who manipulate and care for animals.				
BMBL: A2	A complete clothing change is required In the ABSL-4 operation.				
BMBL: A2	Protective clothing such as uniforms or scrub suits are worn by personnel within the animal facility.				
BMBL: A2	All persons leaving the BSL-4/ABSL-4 laboratory are required to take a personal body shower.				
BMBL: A3	Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas.				
BMBL: A3	Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.				
BMBL: A4	Mechanical pipetting devices must be used.				
BMBL: A5	Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.				
BMBL: A5	When applicable, laboratory supervisors should adopt improved engineering and work practice controls that reduce the risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:				
BMBL: A5-a	Needles and syringes or other sharp instruments are limited for use in the animal facility when there is no alternative for such procedures as parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.				
BMBL: A5-b	Disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: A5-b	Used disposable needles must be carefully placed in puncture-resistant containers used for sharps disposal and placed as close to the work site as possible.				
BMBL: A5-c	Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.				
BMBL: A5-d	Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps.				
BMBL: A5-d	Plasticware should be substituted for glassware whenever possible.				
BMBL: A5-e	Equipment containing sharp edges and corners should be avoided.				
BMBL: A6	Perform all procedures to minimize the creation of splashes and/or aerosols.				
BMBL: A6	Procedures involving the manipulation of infectious materials must be conducted within biological safety cabinets, or other physical containment devices. When procedures can not be performed in a BSC, alternate containment equipment should be used.				
BMBL: A7	Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.				
BMBL: A7	Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual.				
BMBL: A7	All incidents must be reported to the animal facility director, laboratory supervisor, institutional management and appropriate facility safety personnel. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.				
BMBL: A8	Decontaminate all wastes (including animal tissues, carcasses, and contaminated bedding) and other materials before removal from the ABSL-4 laboratory by an effective and validated method.				
BMBL: A8	Laboratory clothing should be decontaminated before laundering.				
BMBL: A8	Supplies and materials needed in the facility must be brought in through a double-door autoclave, fumigation chamber, or airlock.				
BMBL: A8	Supplies and materials that are not brought into the ABSL-4 laboratory through the change room must be brought in through a previously decontaminated double-door autoclave, fumigation chamber, or airlock.				
BMBL: A8	Containment should be maintained at all times.				
BMBL: A8	After securing the outer doors, personnel within the areas where infectious materials and/or animals are housed or are manipulated retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock. These doors must be secured after materials are brought into the facility.				
BMBL: A8	Only necessary equipment and supplies should be taken inside the ABSL-4 laboratory.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: A8	All equipment and supplies taken inside the laboratory must be decontaminated before removal.				
BMBL: A8	Consideration should be given to means for decontaminating routine husbandry equipment and sensitive electronic and medical equipment.				
BMBL: A8	The doors of the autoclave and fumigation chamber are interlocked in a manner that prevents opening of the outer door unless the autoclave has been operated through a decontamination cycle or the fumigation chamber has been decontaminated.				
BMBL: A9	A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory and the animal room/s when infectious agents are present.				
BMBL: A9	The sign must include the animal biosafety level, general occupational health requirements, personal protective equipment requirements, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the animal areas.				
BMBL: A9	Identification of specific infectious agents is recommended when more than one agent is being used within an animal room.				
BMBL: A9	Security sensitive agent information and occupational health requirements should be posted in accordance with the institutional policy.				
BMBL: A9	Advance consideration should be given to emergency and disaster recovery plans, as a contingency for man-made or natural disasters.				
BMBL: A10	An effective integrated pest management program is required.				
BMBL: A11	The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures.				
BMBL: A11	Personnel must receive annual updates or additional training when procedural or policy changes occur.				
BMBL: A11	Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection.				
BMBL: A11	Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.				
BMBL: A12	Animals and plants not associated with the work being performed must not be permitted in the areas where infectious materials and/or animals are housed or are manipulated.				
B					
BMBL: B1	All persons entering the ABSL-4 laboratory must be advised of the potential hazards and meet specific entry/exit requirements.				
BMBL: B1	Only persons whose presence in the laboratory or individual animal rooms is required for scientific or support purposes should be authorized to enter.				
BMBL: B1	Entry into the facility must be limited by means of secure, locked doors.				
BMBL: B1	A logbook, or other means of documenting the date and time of all persons entering and leaving the ABSL-4 laboratory must be maintained.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: B1	While the laboratory is operational, personnel must enter and exit the laboratory through the clothing change and shower rooms except during emergencies.				
BMBL: B1	All personal clothing must be removed in the outer clothing change room.				
BMBL: B1	Laboratory clothing, including undergarments, pants, shirts, jumpsuits, shoes, and gloves, must be used by all personnel entering the laboratory.				
BMBL: B1	All persons leaving the ABSL-4 laboratory are required to take a personal body shower.				
BMBL: B1	Used laboratory clothing must not be removed from the inner change room through the personal shower. These items must be treated as contaminated materials and decontaminated before laundering or disposal.				
BMBL: B1	After the laboratory has been completely decontaminated by validated method, necessary staff may enter and exit the laboratory without following the clothing change and shower requirements described above.				
BMBL: B1	Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.				
BMBL: B2	Animal facility personnel and support staff must be provided occupational medical services, including medical surveillance and available immunizations for agents handled or potentially present in the laboratory.				
BMBL: B2	A system must be established for reporting and documenting laboratory accidents, exposures, employee absenteeism and for the medical surveillance of potential laboratory-acquired illnesses. An essential adjunct to an occupational medical system is the availability of a facility for the isolation and medical care of personnel with potential or known laboratory-acquired illnesses.				
BMBL: B3	Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.				
BMBL: B3	The animal facility supervisor is responsible for ensuring that animal personnel:				
BMBL: B4-a	Receive appropriate training in the practices and operations specific to the animal facility, such as animal husbandry procedures, potential hazards present, manipulations of infectious agents, necessary precautions to prevent potential exposures.				
BMBL: B4-b	The animal facility supervisor is responsible for ensuring that animal personnel: Demonstrate high proficiency in standard and special microbiological practices, and techniques before entering the ABSL-4 facility or working with agents requiring BSL 4 containment.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: B4-c	The animal facility supervisor is responsible for ensuring that animal personnel: Receive annual updates and additional training when procedure or policy changes occur. Records are maintained for all hazard evaluations and employee training.				
BMBL: B5	Removal of biological materials that are to remain in a viable or intact state from the ABSL-4 laboratory must be transferred to a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container. These materials must be transferred through a disinfectant dunk tank, fumigation chamber, or decontamination shower. Once removed, packaged viable material must not be opened outside BSL-4 containment unless inactivated by a validated method.				
BMBL: B6	Laboratory equipment must be routinely decontaminated, as well as after spills, splashes, or other potential contamination.				
BMBL: B6	Equipment, cages, and racks should be handled in manner that minimizes contamination of other areas.				
BMBL: B6	Cages are autoclaved or thoroughly decontaminated before they are cleaned and washed.				
BMBL: B6-a	All equipment and contaminated materials must be decontaminated before removal from the animal facility.				
BMBL: B6-a	Equipment must be decontaminated using an effective and validated method before repair, maintenance, or removal from the animal facility.				
BMBL: B6-b	Equipment or material that might be damaged by high temperatures or steam must be decontaminated using an effective and validated procedure such as gaseous or vapor method in an airlock or chamber designed for this purpose.				
BMBL: B6-c	Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.				
BMBL: B6-c	A spill procedure must be developed and posted within the laboratory.				
BMBL: B6-c	Spills and accidents of potentially infectious materials must be immediately reported to the animal facility and laboratory supervisors or personnel designated by the institution.				
BMBL: B7	The doors of the autoclave and fumigation chamber are interlocked in a manner that prevents opening of the outer door unless the autoclave/decontamination chamber has been operated through a decontamination cycle or the fumigation chamber has been decontaminated.				
BMBL: B8	Daily inspections of essential containment and life support systems must be completed before laboratory work is initiated to ensure that the laboratory and animal facilities are operating according to its established parameters.				
BMBL: B9	Practical and effective protocols for emergency situations must be established. These protocols must include plans for medical emergencies, facility malfunctions, fires, escape of animals within the ABSL-4 laboratory, and other potential emergencies.				
BMBL: B9	Training in emergency response procedures must be provided to emergency response personnel according to institutional policies.				
BMBL: B10	Based on site-specific risk assessment, personnel assigned to work with infected animals may be required to work in pairs.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: B10	Procedures to reduce possible worker exposure must be instituted, such as use of squeeze cages, working only with anesthetized animals, or other appropriate practices.				
C					
BMBL: C(A)	**Cabinet Laboratory**				
BMBL: C1	All manipulations of infectious animals and materials within the laboratory must be conducted in the Class III BSC.				
BMBL: C1	Double-door, pass through autoclaves must be provided for decontaminating materials passing out of the Class III BSC(s).				
BMBL: C1	The autoclave doors must be interlocked so that only one can be opened at any time and be automatically controlled so that the outside door to the autoclave can only be opened after the decontamination cycle has been completed.				
BMBL: C1	The Class III cabinet must also have a pass-through dunk tank, fumigation chamber, or equivalent decontamination method so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the cabinet.				
BMBL: C1	Containment must be maintained at all times.				
BMBL: C1	The Class III cabinet must have a HEPA filter on the supply air intake and two HEPA filters in series on the exhaust outlet of the unit.				
BMBL: C1	There must be gas tight dampers on the supply and exhaust ducts of the cabinet to permit gas or vapor decontamination of the unit.				
BMBL: C1	Ports for injection of test medium must be present on all HEPA filter housings.				
BMBL: C1	The interior of the Class III cabinet must be constructed with smooth finishes that can be easily cleaned and decontaminated. All sharp edges on cabinet finishes must be eliminated to reduce the potential for cuts and tears of gloves.				
BMBL: C1	Equipment to be placed in the Class III cabinet should also be free of sharp edges or other surfaces that may damage or puncture the cabinet gloves.				
BMBL: C1	Class III cabinet gloves must be inspected for leaks periodically and changed if necessary.				
BMBL: C1	Gloves should be replaced annually during cabinet recertification.				
BMBL: C1	The cabinet should be designed to permit maintenance and repairs of cabinet mechanical systems (refrigeration, incubators, centrifuges, etc.) to be performed from the exterior of the cabinet whenever possible.				
BMBL: C1	Manipulation of high concentrations or large volumes of infectious agents within the Class III cabinet should be performed using physical containment devices inside the cabinet whenever practical. Such materials should be centrifuged inside the cabinet using sealed rotor heads or centrifuge safety cups.				
BMBL: C1	The interior of the Class III cabinet as well as all contaminated plenums, fans and filters must be decontaminated using a validated gaseous or vapor method.				
BMBL: C1	The Class III cabinet must be certified at least annually.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: C1	Restraint devices and practices that reduce the risk of exposure during animal manipulations should be used where practicable (e.g., physical restraint devices, chemical restraint medications, mesh or Kevlar gloves, etc.).				
BMBL: C2	Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls must be worn by workers when in the laboratory.				
BMBL: C2	No personal clothing, jewelry, or other items except eyeglasses should be taken past the personal shower area.				
BMBL: C2	All protective clothing must be removed in the dirty side change room before showering.				
BMBL: C2	Reusable laboratory clothing must be autoclaved before being laundered.				
BMBL: C3	Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.				
BMBL: C3	Prescription eye glasses must be decontaminated before removal thought the personal body shower.				
BMBL: C4	Gloves must be worn to protect against breaks or tears in the cabinet gloves.				
BMBL: C4	Gloves must not be worn outside the laboratory.				
BMBL: C4	Alternatives to latex gloves should be available.				
BMBL: C4	Do not wash or reuse disposable gloves.				
BMBL: C4	Dispose of used gloves with other contaminated waste.				
BMBL: C(B)	**Suit Laboratory**				
BMBL: C1	Infected animals should be housed in a primary containment system (such as open cages placed in ventilated enclosures, solid wall and bottom cages covered with filter bonnets and opened in laminar flow hoods, or other equivalent primary containment systems).				
BMBL: C1	All procedures must be conducted by personnel wearing a one-piece positive pressure suit ventilated with a life support system.				
BMBL: C1	All manipulations of potentially infectious agents must be performed within a Class II BSC or other primary barrier system.				
BMBL: C1	Infected animals should be handled within a primary barrier system, such as a Class II BSC or other equivalent containment system.				
BMBL: C1	Equipment that may produce aerosols must be contained in devices that exhaust air through HEPA filtration before being discharged into the laboratory.				
BMBL: C1	These HEPA filters should be tested annually and replaced as needed.				
BMBL: C1	HEPA filtered exhaust air from a Class II BSC can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: C2	Protective laboratory clothing such as scrub suits must be worn by workers before entering the room used for donning positive pressure suits.				
BMBL: C2	All protective clothing must be removed in the dirty side change room before entering the personal shower.				
BMBL: C2	Reusable laboratory clothing must be autoclaved before being laundered.				
BMBL: C3	Inner gloves must be worn to protect against break or tears in the outer suit gloves.				
BMBL: C3	Disposable gloves must not be worn outside the change area.				
BMBL: C3	Alternatives to latex gloves should be available.				
BMBL: C3	Do not wash or reuse disposable gloves.				
BMBL: C3	Inner gloves must be removed and discarded in the inner change room prior to personal shower.				
BMBL: C3	Dispose of used gloves with other contaminated waste.				
BMBL: C4	Decontamination of outer suit gloves is performed during operations to remove gross contamination and minimize further contamination of the laboratory.				
D					
BMBL: There are two models for Biosafety Level 4 laboratories: (A) the Cabinet Laboratory where all handling of the agent is performed in a Class III Biological Safety Cabinet, and (B) the Suit Laboratory where personnel wear a protective suit. Biosafety Level-4 laboratories may be based on either model or a combination of both models in the same facility. If a combination is used, each type must meet all the requirements identified for that type.					
BMBL: D(A)	**Cabinet Laboratory**				
BMBL: D1	The ABSL-4 cabinet laboratory consists of either a separate building or a clearly demarcated and isolated zone within a building.				
BMBL: D1	Laboratory doors must have locks in accordance with the institutional policies.				
BMBL: D1	Rooms in the ABSL-4 facility must be arranged to ensure sequential passage through an inner (dirty) change area, personal shower and outer (clean) change room prior to exiting the room(s) containing the Class III BSC(s).				
BMBL: D1	An automatically activated emergency power source must be provided at a minimum for the laboratory exhaust system, life support systems, alarms, lighting, entry and exit controls, BSCs, and door gaskets.				
BMBL: D1	Monitoring and control systems for air supply, exhaust, life support, alarms, entry and exit, and security systems should be on an uninterrupted power supply (UPS).				
BMBL: D1	A double-door autoclave, dunk tank, fumigation chamber, or ventilated anteroom/airlock must be provided at the containment barrier for the passage of materials, supplies, or equipment.				
BMBL: D2	A hands-free sink must be provided near the doors of the cabinet room(s) and the inner change rooms.				
BMBL: D2	A sink must be provided in the outer change room.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: D2	All sinks in the room(s) containing the Class III BSC and the inner (dirty) change room must be connected to the wastewater decontamination system.				
BMBL: D3	Walls, floors, and ceilings of the laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion.				
BMBL: D3	The internal surfaces of this shell must be resistant to liquids and chemicals used for cleaning and decontamination of the area.				
BMBL: D3	Floors must be monolithic, sealed and coved.				
BMBL: D3	All penetrations in the internal shell of the laboratory and inner change room must be sealed.				
BMBL: D3	Openings around doors into the cabinet room and inner change room must be minimized and capable of being sealed to facilitate decontamination.				
BMBL: D3	All drains in ABSL-4 laboratory area floor must be connected directly to the liquid waste decontamination system.				
BMBL: D3	Services that penetrate the walls, floors or ceiling, plumbing or otherwise, must ensure that no backflow from the laboratory occurs.				
BMBL: D3	Services must be sealed and be provided with redundant backflow prevention. Consideration should be given to locating these devices outside of containment.				
BMBL: D3	Atmospheric venting systems must be provided with two HEPA filters in series and are sealed up to the second filter.				
BMBL: D3	Decontamination of the entire cabinet must be performed using a validated gaseous or vapor method when there have been significant changes in cabinet usage, before major renovations or maintenance shut downs, and in other situations, as determined by risk assessment.				
BMBL: D3	Selection of the appropriate materials and methods used for decontamination must be based on the risk assessment of the biological agents in use.				
BMBL: D4	Laboratory furniture must be of simple construction, capable of supporting anticipated loading and uses.				
BMBL: D4	Spaces between benches, cabinets, and equipment must be accessible for cleaning and decontamination.				
BMBL: D4	Chairs and other furniture should be covered with a non-porous material that can be easily decontaminated.				
BMBL: D5	Windows must be break-resistant and sealed.				
BMBL: D6	If Class II BSCs are needed in the cabinet laboratory, they must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations.				
BMBL: D6	Class II BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.				
BMBL: D7	Central vacuum systems are not recommended. If, however, there is a central vacuum system, it must not serve areas outside the cabinet room.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: D7	Two in-line HEPA filters must be placed near each use point.				
BMBL: D7	Filters must be installed to permit in-place decontamination and replacement.				
BMBL: D8	An eyewash station must be readily available in the laboratory.				
BMBL: D9	A dedicated non-recirculating ventilation system is provided.				
BMBL: D9	Only laboratories with the same HVAC requirements (i.e., other BSL-4 labs, ABSL-4, BSL-3 Ag labs) may share ventilation systems if each individual laboratory system is isolated by gas tight dampers and HEPA filters.				
BMBL: D9	The supply and exhaust components of the ventilation system must be designed to maintain the ABSL-4 laboratory at negative pressure to surrounding areas and provide differential pressure/directional airflow between adjacent areas within the laboratory.				
BMBL: D9	Redundant supply fans are recommended. Redundant exhaust fans are required.				
BMBL: D9	Supply and exhaust fans must be interlocked to prevent positive pressurization of the laboratory.				
BMBL: D9	The ventilation system must be monitored and alarmed to indicate malfunction or deviation from design parameters.				
BMBL: D9	A visual monitoring device must be installed near the clean change room so proper differential pressures within the laboratory may be verified.				
BMBL: D9	Supply air to and exhaust air from the cabinet room, inner change room, and fumigation/decontamination chambers must pass through HEPA filter(s).				
BMBL: D9	The air exhaust discharge must be located away from occupied spaces and building air intakes.				
BMBL: D9	All HEPA filters should be located as near as practicable to the cabinet laboratory in order to minimize the length of potentially contaminated ductwork.				
BMBL: D9	All HEPA filters must be tested and certified annually.				
BMBL: D9	The HEPA filter housings should be designed to allow for in situ decontamination and validation of the filter prior to removal.				
BMBL: D9	The design of the HEPA filter housing must have gas-tight isolation dampers; decontamination ports, and ability to scan each filter assembly for leaks.				
BMBL: D10	HEPA filtered exhaust air from a Class II BSC can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to the manufacturer's recommendations. Biological safety cabinets can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection.				
BMBL: D10	Provisions to assure proper safety cabinet performance and air system operation must be verified.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: D10	Class III BSCs must be directly and independently exhausted through two HEPA filters in series.				
BMBL: D10	Supply air must be provided in such a manner that prevents positive pressurization of the cabinet.				
BMBL: D11	Pass through dunk tanks, fumigation chambers, or equivalent decontamination methods must be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the cabinet room(s).				
BMBL: D11	Access to the exit side of the pass though shall be limited to those individuals authorized to be in the ABSL-4 laboratory.				
BMBL: D12	Liquid effluents from cabinet room sinks, floor drains, autoclave chambers, and other sources within the cabinet room must be decontaminated by a proven method, preferably heat treatment, before being discharged to the sanitary sewer.				
BMBL: D12	Decontamination of all liquid wastes must be documented.				
BMBL: D12	The decontamination process for liquid wastes must be validated physically and biologically.				
BMBL: D12	Biological validation must be performed annually or more often as required by institutional policy.				
BMBL: D12	Effluents from showers and toilets may be discharged to the sanitary sewer without treatment.				
BMBL: D13	A double-door autoclave must be provided for decontaminating waste or other materials passing out of the cabinet room.				
BMBL: D13	Autoclaves that open outside of the laboratory must be sealed to the wall.				
BMBL: D13	This bioseal must be durable, airtight, and sealed to the wall.				
BMBL: D13	Positioning the bioseal so that the equipment can be accessed and maintained from outside the laboratory is recommended.				
BMBL: D13	The autoclave doors must be interlocked so that only one can be opened at any time and be automatically controlled so that the outside door can only be opened after the autoclave decontamination cycle has been completed.				
BMBL: D13	Gas and liquid discharge from the autoclave chamber must be decontaminated.				
BMBL: D13	When feasible, autoclave decontamination processes should be designed so that over-pressurization cannot release unfiltered air or steam exposed to infectious material to the environment.				
BMBL: D14	The ABSL-4 facility design parameters and operational procedures must be documented.				
BMBL: D14	The facility must be tested to verify that the design and operational parameters have been met prior to operation.				
BMBL: D14	Facilities must also be re-verified annually.				
BMBL: D14	Verification criteria should be modified as necessary by operational experience.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: D15	Appropriate communication systems must be provided between the ABSL-4 laboratory and the outside (e.g., voice, fax, and computer). Provisions for emergency communication and access/egress must be considered.				
BMBL: D(B)	**Suit Laboratory**				
BMBL: D1	The ABSL-4 suit laboratory consists of either a separate building or a clearly demarcated and isolated zone within a building.				
BMBL: D1	Laboratory doors must have locks in accordance with the institutional policies.				
BMBL: D1	Rooms in the facility must be arranged to ensure exit sequential passage through the chemical shower, inner (dirty) change room, personal shower, and outer (clean) changing area.				
BMBL: D1	Entry to this area must be through an airlock fitted with airtight doors.				
BMBL: D1	Personnel who enter this area must wear a positive pressure suit ventilated by a life support system with HEPA filtered breathing air.				
BMBL: D1	The breathing air system must have redundant compressors, failure alarms and emergency backup system.				
BMBL: D1	A chemical shower must be provided to decontaminate the surface of the positive pressure suit before the worker leaves the ABSL-4 laboratory.				
BMBL: D1	In the event of an emergency exit or failure of chemical shower, a method for decontaminating positive pressure suits, such as a gravity fed supply of chemical disinfectant, is needed.				
BMBL: D1	An automatically activated emergency power source must be provided at a minimum for the laboratory exhaust system, life support systems, alarms, lighting, entry and exit controls, BSCs, and door gaskets.				
BMBL: D1	Monitoring and control systems for air supply, exhaust, life support, alarms, entry and exit, and security systems should be on a UPS.				
BMBL: D1	A double-door autoclave, dunk tank, or fumigation chamber must be provided at the containment barrier for the passage of materials, supplies, or equipment.				
BMBL: D2	Sinks inside the ABSL-4 laboratory should be placed near procedure areas and contain traps and be connected to the wastewater decontamination system.				
BMBL: D3	Walls, floors, and ceilings of the ABSL-4 laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion.				
BMBL: D3	The internal surfaces of this shell must be resistant to liquids and chemicals used for cleaning and decontamination of the area.				
BMBL: D3	Floors must be monolithic, sealed and coved.				
BMBL: D3	All penetrations in the internal shell of the laboratory, suit storage room and the inner change room must be sealed.				
BMBL: D3	Drains if present, in the laboratory floor must be connected directly to the liquid waste decontamination system.				
BMBL: D3	Sewer vents and other service lines must be protected by two HEPA filters in series and have protection against insect and animal intrusion.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: D3	Services, plumbing or otherwise that penetrate the laboratory walls, floors, ceiling, plumbing or otherwise, must ensure that no backflow from the laboratory occurs.				
BMBL: D3	These penetrations must be fitted with two (in series) backflow prevention devices.				
BMBL: D3	Consideration should be given to locating these devices outside of containment.				
BMBL: D3	Atmospheric venting systems must be provided with two HEPA filters in series and be sealed up to the second filter.				
BMBL: D3	Decontamination of the entire laboratory must be performed using a validated gaseous or vapor method when there have been significant changes in laboratory usage, before major renovations or maintenance shut downs, and in other situations, as determined by risk assessment.				
BMBL: D4	Laboratory furniture must be of simple construction, capable of supporting anticipated loading and uses.				
BMBL: D4	Spaces between benches, cabinets, and equipment must be accessible for cleaning, decontamination and unencumbered movement of personnel.				
BMBL: D4	Chairs and other furniture should be covered with a non-porous material that can be easily decontaminated.				
BMBL: D4	Sharp edges and corners should be avoided.				
BMBL: D5	Windows must be break-resistant and sealed.				
BMBL: D6	BSCs and other primary containment barrier systems must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations.				
BMBL: D6	BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.				
BMBL: D7	Central vacuum systems are not recommended. If, however, there is a central vacuum system, it must not serve areas outside the ABSL-4 laboratory.				
BMBL: D7	Two in-line HEPA filters must be placed near each use point.				
BMBL: D7	Filters must be installed to permit in-place decontamination and replacement.				
BMBL: D8	An eyewash station must be readily available in the laboratory area for use during maintenance and repair activities.				
BMBL: D9	A dedicated non-recirculating ventilation system is provided.				
BMBL: D9	Only laboratories with the same HVAC requirements (i.e., other BSL-4 labs, ABSL-4, BSL-3 Ag labs) may share ventilation systems if each individual laboratory system is isolated by gas tight dampers and HEPA filters.				
BMBL: D9	The supply and exhaust components of the ventilation system must be designed to maintain the BSL-4/ABSL-4 laboratory at negative pressure to surrounding areas and provide differential pressure/directional airflow between adjacent areas within the laboratory.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
BMBL: D9	Redundant supply fans are recommended. Redundant exhaust fans are required.				
BMBL: D9	Supply and exhaust fans must be interlocked to prevent positive pressurization of the laboratory.				
BMBL: D9	The ventilation system must be monitored and alarmed to indicate malfunction or deviation from design parameters.				
BMBL: D9	A visual monitoring device must be installed near the clean change room so proper differential pressures within the laboratory may be verified.				
BMBL: D9	Supply air to the ABSL-4 laboratory, including the decontamination shower, must pass through a HEPA filter.				
BMBL: D9	All exhaust air from the BSL-4/ABSL-4 suit laboratory, decontamination shower and fumigation or decontamination chambers must pass through two HEPA filters, in series before discharge to the outside.				
BMBL: D9	The exhaust air discharge must be located away from occupied spaces and air intakes.				
BMBL: D9	All HEPA filters must be located as near as practicable to the areas where infectious materials and/or animals are housed or are manipulated in order to minimize the length of potentially contaminated ductwork.				
BMBL: D9	All HEPA filters must be tested and certified annually.				
BMBL: D9	The HEPA filter housings are designed to allow for in situ decontamination and validation of the filter prior to removal.				
BMBL: D9	The design of the HEPA filter housing must have gas-tight isolation dampers; decontamination ports; and ability to scan each filter assembly for leaks.				
BMBL: D10	HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to the manufacturer's recommendations. Biological safety cabinets can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection.				
BMBL: D10	Provisions to assure proper safety cabinet performance and air system operation must be verified.				
BMBL: D11	Pass through dunk tanks, fumigation chambers, or equivalent decontamination methods must be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the BSL-4 laboratory.				
BMBL: D11	Access to the exit side of the pass-through shall be limited to those individuals authorized to be in the ABSL-4 laboratory.				
BMBL: D12	Liquid effluents from chemical showers, sinks, floor drains, autoclave chambers, and other sources within the laboratory must be decontaminated by a proven method, preferably heat treatment, before being discharged to the sanitary sewer.				

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		Yes	No	N/A	
BMBL: D12	Decontamination of all liquid wastes must be documented.				
BMBL: D12	The decontamination process for liquid wastes must be validated physically and biologically.				
BMBL: D12	Biological validation must be performed annually or more often as required by institutional policy.				
BMBL: D12	Effluents from personal body showers and toilets may be discharged to the sanitary sewer without treatment.				
BMBL: D13	A double-door, pass through autoclave(s) must be provided for decontaminating materials passing out of the cabinet laboratory.				
BMBL: D13	Autoclaves that open outside of the laboratory must be sealed to the wall through which the autoclave passes.				
BMBL: D13	This bioseal must be durable and airtight.				
BMBL: D13	Positioning the bioseal so that the equipment can be accessed and maintained from outside the laboratory is strongly recommended.				
BMBL: D13	The autoclave doors must be interlocked so that only one can be opened at any time and be automatically controlled so that the outside door to the autoclave can only be opened after the decontamination cycle has been completed.				
BMBL: D13	The size of the autoclave should be sufficient to accommodate the intended usage, equipment size, and potential future increases in cage size.				
BMBL: D13	Autoclaves should facilitate isolation for routine servicing.				
BMBL: D13	Gas and liquid discharge from the autoclave chamber must be decontaminated.				
BMBL: D13	When feasible, autoclave decontamination processes should be designed so that over-pressurization cannot release unfiltered air or steam exposed to infectious material to the environment.				
BMBL: D14	The BSL-4 facility design parameters and operational procedures must be documented.				
BMBL: D14	The facility must be tested to verify that the design and operational parameters have been met prior to operation.				
BMBL: D14	Facilities must also be re-verified.				
BMBL: D14	Verification criteria should be modified as necessary by operational experience.				
BMBL: D14	Consider placing ABSL-4 areas away from exterior walls of buildings to minimize the impact from the outside environmental and temperatures.				
BMBL: D15	Appropriate communication systems must be provided between the laboratory and the outside (e.g., voice, fax, and computer). Provisions for emergency communication and access/egress should be considered.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
Inspector summary and comments:					
Recommendations:					
Inspector completing checklist:					**Date:**
Other inspectors present:					**Date:**